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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,276	04/24/2001	John R. Hadcock	PC10834ATMC	6011

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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/841,276	Applicant(s) HADCOCK, JOHN R.	
	Examiner Christopher Nichols, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *3,4,6 and 9-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5, 7, and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with **traverse** of Group I (claims 1, 2, 5, 7, and 8, each in part) drawn to a method of treating obesity comprising administering a neurotensin-1 agonist to a patient who is, or is at risk of becoming obese in Paper No. 8 (30 December 2002) is acknowledged. The traversal is on the ground(s) that a search of Group I and Group VII does not constitute a search burden. This is not found persuasive because Group I is drawn to a method of using a neurotensin-1 agonist which runs the gamut of organic, inorganic compounds, peptides, antibodies, polynucleotides, for instance. Group VII is a pharmaceutical composition of a yet unclear neurotensin-1 agonist and a second compound which is useful for the treatment of obesity, diabetes, sexual dysfunction, arteriosclerosis, insulin resistance, impaired glucose tolerance, hypercholesterolemia, or hypertrigylceridemia. The search and consideration of the "second compound" of Group VII is not only a replication of the search for Group I but also a far more extensive search including several disorders in addition to obesity. Thus, rejoinder of Groups I and VII constitutes a search burden on the examiner. Claims 3, 4, 6, and 9-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected material, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8 (30 December 2002). The requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, and/or Claims

2. The Preliminary Amendment of Paper No. 8 (30 December 2002) has been entered in full. Claim 11 has been amended, claims 3-4, 6, and 9-16 are withdrawn from consideration as discussed above, and claims 1-2, 5, and 7-8 are under examination.

3. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1647, Examiner Christopher Nichols.

Information Disclosure Statement

4. The information disclosure statement filed 7 December 2001 (Paper No. 5) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because citation EP 0647629 is not in the English language. This citation has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 5, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1, 2, 5, 7, and 8 are directed to a method of treating obesity comprising administering a neurotensin(-1) agonist or ligand to an obese patient or a patient at risk of becoming obese.

6. The specification asserts that neurotensin receptor ligands or agonists can be used to treat obesity, but provides no nexus between neurotensin receptors (or their ligands/agonists) and obesity. The specification provides general guidance regarding drug formulations and assays for neurotensin receptor agonist's activity. No working examples are provided wherein a neurotensin receptor ligand or agonist is administered successfully to treat obesity.

7. The art also does not clearly indicate that neurotensin receptor ligands/agonists can be used to successfully treat obesity. US 6274720 teaches that defects in the processing of the proneurotensin/neuromedin gene have been correlated with the onset of obesity in mice homozygous for a mutation in the carboxypeptidase E gene. Also, the transgenic mice have 80% less NT and NN in hypothalamic fluid versus normal mice. Also, high levels of partially processed pro-NT/NN were present in the samples taken from the mutant mice (Col. 2 lines 55-65). It is of note that the transgenic obese mice were not treated by the administration of NT/NM.

8. In addition, Boules et al. [(18 May 2000) "A novel neurotensin peptide analog given extracranially decreases food intake and weight in rodents." Brain Research 865(1): 35-44] teaches that: "To date no one has been able to test the long term effects of NT on food intake and

weight loss because NT is readily degraded by peptidases and needs to be injected directly into the brain, in addition to the fact that there was no NT agonist that has NT-like activity and has the ability to cross the blood-brain barrier." (pp. 36) It is not evident from the specification that the instant application has adequately addressed these obstacles.

9. The breadth of the claims is large. Regarding agent, the art recognizes that "agent" can pertain to chemical entities, pharmaceutical compositions, proteins, peptides, non-peptide compounds, animal tissue extracts, vegetable extracts, cell extracts, synthetic agents, biologically derived substances as well as proteinaceous substances, known, and unknown compounds. Due to the large quantity of experimentation necessary to identify all the applicable compounds, ligands, and/or agonists, the lack of direction/guidance presented in the specification regarding synthesizing, screening, and evaluating all applicable compounds, ligands, and/or agonists, the absence of working examples directed to known agents, the complex nature of the invention, the unpredictability of the effects of compounds, ligands, and/or agonists on cells [Hong et al. (1997) "Design, synthesis and pharmacological evaluation of active pyrrole based, nonpeptide analogues of neurotensin(8-13). J. Chem. Soc. (Perkin Trans. 1): 2997-3003], and the breadth of the claims which fail to recite limitations for what constitutes an applicable compounds, ligands, and/or agonists, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

10. Therefore, due to the large quantity of experimentation required to determine how to successfully treat obesity with NT receptor ligands/agonists, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art setting forth the obstacles of treating

obesity with NT receptor ligands/agonists, and the large breadth of the claims, undo experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Summary

11. Claims 1, 2, 5, 7, and 8 are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher J. Nichols whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmerer

CJN
February 21, 2003